## REMARKS

By the *Office Action* of 17 November 2004, Claims 1-23 are pending in the Application, and all rejected. By the present *Response And Amendment*, the Applicant amends and cancels some Claims, provides new Claims, and presents several distinguishing features between the Claims as presently written and the cited references, and in so doing, believes the rejection of the Claims in view of the cited art is overcome.

### 1. The Present Invention

The present invention is a clinical operational (measures clinical, utilization and cost) information management system. In a preferred embodiment of the present invention, as illustrated in **Fig. 3**, the process is begun by allocating a "first set" of a specific "resource" for a "specific clinical procedure". In an example, the resource can be Medusa tubing (or other disposable products that, for example, might be opened during a procedure, yet not utilized during the procedure), the first set being a specific amount (number) of tubing on-hand during the procedure before the implementation of the present invention, and the specific clinical procedure can be a coronary artery bypass (CABG).

The present invention provides a system for identifying practice patterns of how a procedure is performed to establish benchmark costs and facilitate resource allocation and utilization based on clinical considerations. Thus, upon review of the amount of a resource actually used during a procedure, the present method provides a "second set", or benchmark, of the resource to be allocated when the same procedure is subsequently performed, such that waste of unnecessary products is reduced. Reducing the products required for a procedure, reduces cost. Reduction of cost that can be specifically measured by the product cost, and that reduction in cost can be shared with the hospital and the procedure physicians saving the money..

The essence of the present invention, in the example as outlined above, is to collect data with the ***actual*** utilization of each item (i.e. Medusa tubing) during ***actual*** CABG procedures, determine reduction opportunities that would eliminate waste, establish a benchmark for the average utilization of Medusa tubing during CABG procedures, and then standardized future CABG procedures to include only the necessary amount (number) of tubing per CABG procedures, which can then be requisitioned for future procedures. If the procedure was a CABG with a Mitral Valve Replacement, the procedure category would be different.

The *Specification* provides a more detailed account of a preferred method:

> The present invention determines where the inefficient and ineffective aspects of a hospital exist. Once these aspects are located, a more profitable and improved quality practice may be developed. Fig. 3 illustrates a flowchart of one embodiment of a method 300 for measuring the operational efficiency and effectiveness of a clinical practice. The method 300 is implemented by allocating 310 the resources and conducting 320 a medical procedure. Then, in process block 330, the data from allocating the recourses and conducting the procedure is collected and stored in the database. For example, the costs associated with conducting a procedure are maintained to provide cost [opportunity information] in the future. Process blocks 310, 320 and 330 create a continuous loop wherein resources are allocated for the next procedure and data is collected for each of the procedures conducted at the medical facility.
>
> After a procedure is completed, the process continues to block 340 where potential waste and cost reduction opportunities are identified as well as clinical outcomes. For example, because quality control monitors when a drug is to be used or may not be used, physicians may be rewarded for using the drug properly. Based upon the identified waste and cost reduction opportunities, a benchmark is established 350 as to the average utilization of resources for a particular type of procedure. The resources may be, for example, supplies, the type of room required, the number of hours the room is required, the number and type of assistant or staff personnel required, etc.
>
> Once a benchmark is established, particular types of procedures may be standardized to include only necessary resources which are then requisitioned for future procedures based upon the benchmark requirements established for the standardized procedure. Supplies may be requested on a scheduled-basis based upon the benchmark requirements. Blocks 360 and 370 illustrate the steps of standardizing a procedure and requisitioning resources for a standardized procedure, respectively. The procedures are standardized by eliminating unnecessary resources as determined by the benchmarks. *Page 10, Line 24 – Page 12, Line 3.*

Once the benchmarks are established and procedures are standardized, supplies may be requisitioned automatically from vendors, the supply room, or upon the scheduling of a clinical procedure. Physicians are given information specific information on how their product usage differs from the best practice identified. Also, the costs associated with the utilization of supplies are monitored to determine if cost of supplies and use of supplies are within benchmark parameters. *See, Page 12, Lines 3-11.*

Each procedure has its own costs and opportunities for standardization. For example, the cardiac operating rooms are measured and evaluated by the total number of procedures in a

particular category (i.e. CABG, Mitral Valve Replacement, etc.) during a defined time period to determine the average benchmark operating room cost for that procedure. Operating costs are then next measured during the period and divided by the total number of procedures in each category during the period to determine the average actual procedure room for each clinical category. The average benchmark procedure costs are compared to average actual procedure costs for each category to determine the average procedure savings for each category. All cost savings are evaluated with clinical considerations. Then, fifty percent (50%) of the savings in each category may be shared with physicians. *See, Page 12, Line 12 – Page 13, Line 3.*

The present invention is distinguishable from the prior art that focuses on a "macroeconomic scale", as it provides methodologies on a "microeconomic scale". The present invention is based on ***specific*** procedures performed on patients, not a "roll-up" of procedures under prior art "coding" methods, wherein coding assigns many types of patients groups into the same procedure codes. Thus, savings are at the specific and particular procedure levels, not groups of procedures under a common heading.

The present invention sets benchmarks not in the abstract, but with specificity, for example, to determine supplies needed to complete a specific procedure, the number of hours to complete a specific procedure, and the number of staff required for a specific procedure to be performed. Each benchmark is related to a specific clinical procedure. These benchmarks are related to the actual care of the same type of patient, with the same type of procedure, benchmarked at a detailed cost and quality level. *See, Specification, Page 17, Lines 5-20.*

**2. US Patent No. 5,778,345 to McCartney**

The present invention is patentably distinct from McCartney. Unlike the presently claimed invention that recites a focus on *specific clinical procedures*, procedures in McCartney rely on an ICD-9 and DRG generated "code", which mixes many different procedures together. As discussed, coding assigns many types of patients groups into the same procedure codes. The present invention is based on the specific procedure performed on the patient, not a "roll-up" of procedures like those disclosed in McCartney. In addition, cost data is not utilized in the McCartney model.

In McCartney, an example of a DRG generated code would be DRG 104: Cardiac Valve Replacement with Cardiac Catheterization Procedure. Yet, such a generality as applied to the

present invention (for example, as disclosed at *Page 10*), would "roll-up" all of these procedures to this one DRG. The ICD-9 code cited by McCartney would utilize one code (35.2) for the seven categories of procedures separately listed out at *Page 10*.

The present invention goes beyond the McCartney general approach to an accumulated patient record. Each of the present records is specific, and allows for "apple to apple" comparisons. As demonstrated at *Pages 17-30*, the present application illustrates that patient records can include the precise utilization of items by the exact procedure performed. That is, McCartney is described as macroeconomic in scale, in contrast to the present invention which is microeconomic.

Further, in contrast to the benchmarks of the present method, McCartney discloses that the benchmark data points are general healthcare measurements that allow hospitals and planners to determine how many physicians or beds are needed in a market area.

These distinctions are clarified in the pending Claims.

**3. US Patent No. 5,835,897 to Dang**

The present invention is also patentably distinct from Dang. First, Dang, as in McCartney, works from data generated from DRG and ICD9 code data. This is very different from the level of data captured in the present invention. In just one example, Dang discloses Ischemic heart disease with valvular procedure. In a patentable contrast, the present invention would detail all the different types of valvular procedures as seen beginning on *Page 14, Lines 10*. Dang utilizes these very general categories to drive the comparison benchmark data. In contrast, the present invention as claimed drives the data to a comparison on the exact procedure level with comparisons based on utilization of actual products utilized.

Further, the terms "cost" and "utilization" at *Col. 19, Lines 50-55* refer to monitoring aggregate patient data. In Dang, the word cost is synonymous with the charges for care. For example, the cost would be the number of times a pneumonia patient is seen by a primary care physician. A general cost number is used across the patient populations to see how often a pneumonia patient is seen by a physician. Prevalence and incidence rates are used as predictive tools.

For the present invention, the term "benchmarking" is the measurement of ***actual*** patient procedure combined with the ***actual*** products utilized. Both quality and cost of the particular

case can be benchmarked against the exact type of cases. *See Specification, Page 7, Line 17.* Definitions for patient types begin on this page, and outcomes of a particular case continue. *Pages 8-10.* The present invention as claimed has the ability to compare the actual type of patient with the cost and utilization of product. *Page 11.* The present invention is used to improve the actual quality and cost of the procedure, whereas the Dang methodology is used to be a "predictive tool for planning."

**4. The Pending Claims**

Claims 1 is canceled, and new independent Claim 24 provided. Claim 24 specifically recites a computer-implemented method that relates to a *specific* clinical procedure, as opposed to a set of related procedures that are in the prior art rolled into codes, and then analyzing the "codes" for efficiencies.

New independent Claim 25 is presented to recite a preferred embodiment of the present invention, as generally outlined in the *Abstract* and elsewhere.

**5. Rejection Of The Claims**

Claims 21-22 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. These Claims have been canceled.

Claims 1-20 and 23 are rejected under 35 U.S.C. §101, as being directed to non-statutory subject matter. The remaining Claims of this group have been amended to be "computer-implemented method" Claims, and thus believed to overcome this ground of rejection.

Claims 1, 3-7, 9-18 and 20-23 are rejected under 35 U.S.C. §103(a) as being unpatentable over US Patent No. 5,778,345 to McCartney, in view of US Patent No. 5,835,897 to Dang. Claim 2 is rejected under 35 U.S.C. §103(a) as being unpatentable over McCartney, in view of Dang, and further in view of CostControl. Claims 8 and 19 are rejected under 35 U.S.C. §103(a) as being unpatentable over McCartney, in view of Dang, and further in view of US Patent No. 6,117,073 to Jones et al.

New independent Claims 24 and 25 are believed allowable in view of the above, and likewise those Claims ultimately dependent from Claims 24-25.

Claims 2 and 26 are similar, and each believed allowable as dependent from an allowable Claim, and further patentable as the presently recited method of reducing costs is at a procedure level of each item utilized to take care of a patient. CostControl discloses gainsharing options

where paying the physicians for reduction in cost is illegal on the macro level. Claim 1 is not distinguishable, as it recites a method in-line with, for example, OIG Opinions 01-01, 05-01, 05-02, 05-03, 05-04 where it is stated that the specificity of the quality and utilization data is at a patient level, and not a macro level. OIGs approval of these opinions outlines the difference in the data of the present invention, and that described in CostControl.

**6. Fees**

This *Response and Amendment* is being filed within six months of the *Office Action*, and more specifically within three months, thus no extension fees are believed due.

This *Response and Amendment* provides the application with less than or equal to the total Claims, and independent Claims, provided upon filing, and thus no claim fees are believed due.

Nonetheless, should any further fees be due, authorization to charge deposit account No. 20-1507 is hereby expressly given.

## CONCLUSION

By the present *Response and Amendment*, the Application has been in placed in full condition for allowance. Accordingly, Applicant respectfully request early and favorable action. Should the Examiner have any questions or reservations, the Examiner is invited to telephone the undersigned Attorney at 404.885.2773.

Respectfully submitted,

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